

Appl. No. 09/430,050

Amdt. AF dated February 27, 2004

Reply to Final Office Action of December 31, 2003

Amendments to the Claims

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims

1. (Previously Presented) A valve for a tubular peel-away sheath having a lumen therethrough comprising:

a valve body having a lumen therethrough;

means for preferentially breaking said valve body along a predetermined location in response to applied force, such that said valve body lumen splits open upon breaking;

means for coupling said valve body to said peel-away sheath for coupling said peel-away sheath lumen to said valve body lumen;

means for receiving a compressible valve sleeve;

a compressible valve sleeve having a proximal end, a distal end, and a lumen adapted to receive a distal portion of a medical device; and

means for compressing said valve sleeve for restricting any fluid flow from said peel-away sheath lumen through said valve and valve sleeve lumen, said proximal end of said compressible valve sleeve extending proximal of said means for compressing said valve sleeve.

2. (Original) A valve as recited in claim 1, wherein said valve sleeve includes a free end extending past said means for compressing, and further comprising means for receiving a catheter tip within said valve sleeve lumen free end while said means for compressing is compressing said valve sleeve, such that said valve sleeve lumen is substantially occluded by said inserted catheter tip while said catheter tip is inserted.

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3. (Previously Presented) A breakaway valve for a tubular peel-away sheath, said sheath having an external surface, a lumen, and a proximal end comprising:

means for reversibly restricting fluid flow from said sheath lumen coupled to said sheath proximal end, wherein said means for reversibly restricting fluid flow includes a compressible valve sleeve and means for compressing said valve sleeve, said valve sleeve having a proximal end and a distal end and a lumen therethrough, the proximal end of said valve sleeve extending proximal of said means for reversibly restricting fluid flow and adapted to admit a catheter distal end into said valve sleeve lumen; and

means for breaking apart said fluid flow restricting means responsive to applied force.

4. (Original) A breakaway valve as recited in claim 3, wherein said means for reversibly restricting flow has an open position for allowing flow therethrough and a closed position for substantially restricting flow, wherein said means for admitting said catheter distal end includes means for admitting said catheter distal end while said means for restricting flow is in said closed position.

5. (Original) A breakaway valve as recited in claim 4, wherein said means for restricting flow includes a flexible, constrictable tube having a lumen therethrough.

6. (Original) A breakaway valve as recited in claim 5, wherein said means for restricting flow includes means for pinching said flexible tube for constricting said flexible tube lumen.

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7. (Original) A breakaway valve as recited in claim 6, wherein said means for pinching has at least two portions movable with respect to each other, said two portions having means for accepting and pinching said flexible tube therebetween, said two portions together having an open position and a closed position.

8. (Original) A breakaway valve as recited in claim 7, wherein said movable pinching member portions are hingedly coupled together with at least one hinge.

9. (Original) A breakaway valve as recited in claim 8, wherein said sheath has a longitudinal axis and said at least one hinge has an axis substantially parallel with said sheath longitudinal axis and said hinge enables movement of said pinching member portions about said hinge longitudinal axis for pinching said flexible tube in said closed position.

10. (Withdrawn) A breakaway valve as recited in claim 8, wherein said sheath has a longitudinal axis and said hinge lies in a plane substantially transverse to said sheath longitudinal axis.

11. (Original) A breakaway valve as recited in claim 8, wherein, when in said closed position, said pinching members include means for leaving sufficient space in said flexible tube lumen for passage of a guide wire.

12. (Previously Presented) An introducer sheath assembly for introducing a catheter distally into a human body comprising:

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a tubular, distal introducer sheath having a proximal region and a lumen therethrough, said sheath having at least one longitudinal strip for preferentially tearing said sheath along said strip;

a tubular, compressible, proximal valve sleeve having a proximal region, a distal region, and a lumen therethrough; and

a valve body having a lumen therethrough and being sealingly coupled to said introducer sheath proximal region, said valve having at least one weakened region for preferentially splitting said valve into at least two pieces responsive to an applied breaking force, said valve body having a seat for mating to said proximal valve sleeve distal region, said valve body including a pinch member for pinching said flexible valve sleeve and having a closed position for constricting fluid flow through said valve sleeve and an open position for admitting a catheter inserted through said valve sleeve; wherein said proximal region of said proximal valve sleeve extends proximal of said pinch member and is adapted to receive a medical device.

13. (Original) An introducer sheath assembly as recited in claim 12, wherein said flexible valve sleeve includes a free portion proximal of said pinch member for admitting said catheter into said sleeve free portion while said pinch member is in said closed position.

14. (Original) An introducer sheath assembly as recited in claim 12, wherein said valve body pinch member includes a recess therein for allowing passage of a guide wire through said pinch member while said pinch member is in said closed position.

15. (Previously Presented) A breakaway valve body for restricting flow from a peel-

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away introducer sheath having a proximal region and a lumen therethrough comprising:

a breakaway distal portion having a lumen therethrough for receiving said introducer sheath proximal region; and

a proximal portion including two opposed valve body members, at least one of which is movable relative to the other and having concave surfaces therebetween for receiving a flexible valve sleeve therebetween, said valve body opposed members having an open position and a closed position, wherein said valve body members move apart relative to each other to reach said open position and said valve body opposed members move together relative to each other to reach said closed position, wherein said flexible sleeve has a lumen therethrough adapted to receive a medical device, said flexible sleeve having a proximal end, and a distal end, said proximal end extending proximal of said body members, said sleeve being compressible, and said sleeve and sleeve lumen are constricted between said body members in said closed position, such that fluid flow through said sleeve is substantially restricted in said closed position.

16. (Withdrawn) A breakaway valve body as recited in claim 15, wherein said valve body members are pivotally mounted on hinges lying in a plane substantially transverse to said valve body lumen longitudinal axis.

17. (Withdrawn) A breakaway valve body as recited in claim 16, wherein at least one of said valve body members includes a notch and said opposing valve body member includes a latch for hooking said latch to said notch for securing said valve body members together in said closed position.

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18. (Withdrawn) A breakaway valve body as recited in claim 16, wherein said valve body members have a proximal end and said valve body members include at least one pinch member for pinching said flexible sleeve therebetween and said pinch member is disposed distally of said valve body proximal end such that a proximal region of said valve body and a proximal region of said flexible sleeve can have a catheter inserted therein while said valve body members are in said closed position.

19. (Withdrawn) A breakaway valve body as recited in claim 18, wherein said valve body members have a proximal end and said valve body members include at least one pinch member for pinching said flexible sleeve therebetween and said pinch member is near said valve body proximal end, wherein said flexible sleeve includes a proximal region extending proximally of said pinch members such that a proximal region of said flexible sleeve can have a catheter inserted therein while said valve body members are in said closed position.

20. (Withdrawn) A breakaway valve body as recited in claim 19, wherein at least one of said pinch members has a recess for allowing passage of a guide wire between said pinch members while in said closed position.

21. (Original) A breakaway valve body as recited in claim 15, wherein said valve body members are pivotally mounted to each other along at least one hinge oriented substantially parallel to said valve body lumen longitudinal axis.

22. (Withdrawn) A breakaway valve body as recited in claim 21, wherein one of said

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valve body members has an internal convex pinch member for pressing an inserted flexible tube against a corresponding internal concave portion of the other body member.

23. (Withdrawn) A breakaway valve body for restricting flow from a peel-away introducer sheath having a proximal region and a lumen therethrough comprising:

a breakaway distal portion having a lumen therethrough for receiving said introducer sheath proximal region; and

a proximal portion including a first valve body member and a second valve body member opposed to said first body member for receiving a flexible valve sleeve therebetween, wherein said first valve body member has a proximal region and a concave inner surface and said second valve body member has an arm hingedly mounted to said first valve body member proximal region and said arm includes an inner pinch member for pressing inward toward said first body member, wherein said arm has a distal ratchet end for mating to a series of notches on said valve body for holding said arm and pinch member in a series of increasingly constrictive pinching positions against said inserted valve sleeve.

24 - 31. (Canceled)